

REMARKS

CLAIM OBJECTION

Applicants have amended claim 3 to remove the typographical error therein.

REJECTION UNDER 35 USC §103

The examiner rejects claims 1-5, 7-9, and 11-12 under 35 USC §103 as being obvious over the combined disclosures of Klimesch et al. (US 4,880,585) in view of Klimesch et al. (US 5,073,379). This rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the examiner must show that the prior art teaches or suggests each claim element, gives some suggestion or motivation to make the claimed invention, and gives a reasonable expectation for success in doing so (see, e.g., *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). The examiner has not made the required showing.

The present claims are drawn to a process for producing pharmaceutical tablets in which

1. an extrudable pharmaceutical mixture is heated and extruded as a continuous product strip;
2. the still deformable product strip is compressed into a continuous tablet belt;
3. the tablet belt is allowed to cool and form a solidified tablet belt;
4. the tablets are mechanically singulated in a continuous process;
5. the tablets are transported further and subsequently deflashed.

Claim 1. Thus, a continuous product strip is extruded and compressed to form a

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continuous tablet belt, the tablet belt is allowed to cool and solidify, and the tablets are then singulated in a continuous process and deflashed.

Klimesch '585, as the examiner has pointed out, teaches extrusion and compression of a product strip to form a tablet belt, the tablets of which, upon cooling, are transported and deflashed. Office Action p.3. That reference does not teach a continuous singulation process. The examiner characterized Klimesch '379 to fill this gap, stating that this reference "shows that it is known to singulate a tablet belt in a continuous process." *Id.* (citing Klimesch '379, fig.1, col.11:8-9). The examiner further states that "[i]t would have been *prima facie* obvious ... to continuously singulate Klimesch '585's tablets, as in Klimesch '379." *Id.*, pp.3-4.

Applicants disagree with the examiner's argument that one of skill in the art would find Klimesch '379 to teach a suitable process for singulation of a cooled tablet belt, such as that produced in the process of Klimesch '585. Coordination of the tablet forming rollers, the transportation means, and the singulating means would need to be precise, to ensure that the indentations of the singulating means match the spacing of the tablet belt. With a solidified tablet belt, even slight deviation would result in massive damage to the tablets. The potentially harmful consequences and the amount of engineering required to avoid these would not suggest that the resulting process would be of true benefit, regardless of the increased proximity that could be achieved.

Further, the present invention actually consciously endeavors to ensure that the solidified and cooled tablet belt is formed as an intermediate step, ensuring safe release of each tablet from the molding rolls. Combining the cited prior art process in

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the manner suggested by the examiner, to maximize spatial efficiency, would give up specific benefits of the present invention, where the solidified and cooled tablet belt is produced intermediately.

As the present invention requires elements not present in the cited prior art, and as the ordinarily skilled artisan would not find adequate motivation or suggestion to combine the cited references, applicants respectfully submit that the present claims are not obvious therefrom. Accordingly, it is respectfully requested that the rejection under 35 USC 103(a) be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, applicants consider that the rejections of record have been obviated and respectfully solicit passage of the application to issue.

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Respectfully submitted,
KEIL & WEINKAUF

A handwritten signature in black ink, appearing to read "David C. Liechty". It is written in a cursive style with some loops and variations in letter form.

David C. Liechty
Reg. No. 48,692

1350 Connecticut Ave., N.W.
Washington, D.C. 20036
(202)659-0100

DCL/lc